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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,498	03/29/2001	Eileen C. Fuchs	112701-200	5214

29157 7590 02/12/2003

BELL, BOYD & LLOYD LLC
P. O. BOX 1135
CHICAGO, IL 60690-1135

EXAMINER

PRATT, HELEN F

ART UNIT	PAPER NUMBER
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1761

DATE MAILED: 02/12/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/821,498

Applicant(s)

FUCHS ET AL.

Examiner

Helen F. Pratt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-12, 15-23, 26-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mark et al. in view of Abbruzzese et al.

The claims are rejected for the reasons of record cited in the last office action

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mark et al. as applied to the above claims, and further in view of Balleve et al. or Kawasaki et al. and Etzel.

The claims are rejected for the reasons of record cited in the last office action.

Claims 13, 14, 24, 25, 35, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mark et al. in view of Abbruzzese et al. as applied to claims 1-4, 6-12, 15-23, 26-34 above, and further in view of Cavaliere et al.

The claims are rejected for the reasons of record cited in the last office action.

ARGUMENTS

Applicant's arguments filed 1-13-02 have been fully considered but they are not persuasive. Applicants argue that Mark et al. does not teach a method for improving muscle protein synthesis and other improvements. However, the use of a protein source to improve muscle protein synthesis is well known as this is the function of protein in the diet. Certainly, the use of lipids and carbohydrates has a protein sparing

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effect as lipids keep protein or tissue from being burned for energy. The above is known nutritional information. No patentable distinction is seen at this time in the use of 18% fat and the lower level of 20% disclosed by the reference. Mark et al. is used in combination with Abbruzzese et al. to show that it is known to use omega 3 fatty acids and vitamin C and E, one of whose function is to act as antioxidants. A metabolically stressed patient as in Abbruzzese et al. is one who would need protein synthesis. Applicants' invention is also directed to stressed individual as those who are ill due to oxidative stress or inflammatory conditions (page 5, lines 16-24). Also, col. 3, lines 40-4, disclose that the protein concentration of the reference is optimal for moderate tissue repair i. e. protein promotes tissue repair. Vitamins E and C are disclosed in the reference and C in more than the daily requirement as is vitamin E (col. 6, lines 55-66 and col. 7, lines 1-30). In fact, Abbruzzese et al. disclose the use of more vitamin E and C per serving (page 14 top of specification compared to col. 7, of Mark et al.) No data is seen that anything unexpected happens in the combination of ingredients, and particular ratios, that more protein synthesis occurs using the instant invention as opposed to the combined references.

Applicants argue as to Abbruzzese that there is no suggestion in Abbruzzese to improve protein syntheses. However, the reference discloses that the nutritional composition is to promote "maintenance and repair of body tissue", i. e. protein synthesis as tissue is made from protein (col. 16, lines 1-12). Also, in col. 7, lines 25-35, the composition is used to provide nutritional support due to nutritional deterioration,

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or to rehabilitate the depleted patient. This would of course include adequate amounts of protein to build tissue.

Applicants argue that Ballevre or Kawasaki or Etzel do not teach the whole invention. However, these references are used to show that it is known to use GMP in nutritional supplements. The reason to use GMP in protein synthesis is that it provides protein nutrition, and provides a hydrolyzed, nonbitter ingredient (col. 3, lines 20-44 of Ezel). The GMP of Kawasaki is another source of protein. Nothing is seen that it produces unexpected results in the instant invention. The GMP of Ballevre et al. can be used in compositions to provide dietary proteins to promote body growth (col. 5, lines 40-44) (this includes production of tissue and muscle provided as a function of proteins).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen F. Pratt whose telephone number is 703-308-1978. The examiner can normally be reached on Monday 4-10, Tuesday and Wednesday, Friday, from 9:30 to 6:00 and Thursday 4-10.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Milton Cano, can be reached on (703) 308-3959. The fax phone number for the organization where this application or proceeding is assigned is 703-305-7718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0651.

Hp 2-5-03


HELEN PRATT
PRIMARY EXAMINER